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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,432	03/20/2001	Raymond J. Taupier JR.	15966-729 (Cura-229)	3506

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BOSTON, MA 02111

EXAMINER

LI, RUIXIANG

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 06/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/813,432

Applicant(s)

TAUPIER ET AL.

Examiner

Ruixiang Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1, 29, 32 and 49-63 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 29, 32, and 49-63 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 19.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### **I. Status of Application, Amendments, and/or Claims**

The amendment filed in Paper No. 17 on April 21, 2003 has been entered in full. Claims 2-4 and 44-48 have been cancelled. Claims 1, 29, and 32 have been amended. Claims 49-63 have been added. Claims 1, 29, 32, and 49-63 are pending and are under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

### **II. Withdrawn Objections and/or Rejections**

Applicants' cancellation of claims 2-4 have made the rejections under 35 U.S.C. § 101/112 moot.

The rejection of claims 1-4, 29 and 32 under 35 U.S.C. 112, 1<sup>st</sup> paragraph for Written Description, as set forth at page 5 of the previous Office Action (Paper No. 15, November 19, 2002), has been withdrawn in view of Applicants' amendment to the claims 1, 29, and 32, and cancellation of claims 2-4.

The rejection of claims 1-4, 29, and 32 under 35 U.S.C. § 102 (b) as being anticipated by Murphy (U.S. patent No. 5,652,133), as set forth at pages 5-6 of the previous Office Action (Paper No. 15, November 19, 2002), has been withdrawn in view of Applicants' amendment to claims 1, 29, and 32, and cancellation of claims 2-4.

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The rejection of claims 1-4, 29, and 32 under 35 U.S.C. § 102 (b) as being anticipated by Charo (U.S. patent No. 5,707,815), as set forth at page 6 of the previous Office Action (Paper No. 15, November 19, 2002), has been withdrawn in view of applicants' amendment to claims 1, 29, and 32, and cancellation of claims 2-4.

### **III. Claim Rejections Under 35 U. S. C. § 101**

The rejection of claims 1, 4, 29, and 32 under 35 U. S. C. § 101, as set forth at pages 2-4 of the previous Office Action (Paper No. 15, November 19, 2002), remains.

Newly added claims 49-63 are also rejected under 35 U. S. C. § 101. The basis for this rejection is set forth at pages 2-4 of the previous Office Action (Paper No. 15, November 19, 2002).

Applicants argue, citing the utility requirement in MPEP, that the Declaration from Dr. Valerie Gerlach states that the polypeptide of SEQ ID NO: 22 can be used to diagnose a specific panoply of breast cancers and metastatic progression of breast cancer, in addition to its use in determining the development stage of the brain in an individual, thus has a specific and substantial utility.

Applicants' argument has been fully considered, but is not deemed to be persuasive because the Declaration from Dr. Valerie Gerlach is insufficient to overcome the utility rejection for the following reasons. First, the two studies performed by Dr. Valerie Gerlach merely measure the RNA level, not protein level, in each sample. A high level of RNA is not necessarily linked to a high level of protein. Thus, the studies fail to provide a utility for the claimed polypeptides. To claim the use of the polypeptide

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of SEQ ID NO: 2 as a diagnostic marker, a specific link between the polypeptide and a certain disease, e.g., breast cancer, must be demonstrated. Secondly, while the nucleic acid encoding the polypeptide of SEQ ID NO: 22 might be used as a diagnostic marker (which likely provides a utility for the nucleic acid), the studies do not support the assertion that gene, protein, antibodies or small molecules therapeutics targeting this gene or its protein product are effective in the treatment of breast cancer (#7 of Declaration). Furthermore, there is no evidence supporting the statement that gene or proteins levels of expression are useful as a marker of brain tissue. Therapeutic modulation of the expression or function of this gene is useful in the treatment of neurological disorders, such as Alzheimer's disease (#6 of declaration). Table AC Panel 1.2 only shows the RNA level in fetal brain and various parts of the brain. There is no indication the sampling source of the various parts of the brain; were they obtained from an adult brain or a fetal brain? There is no indication how many samples were performed. There is no evidence on the RNA levels in brain tissues at different development stages.

In summary, the Declaration from Dr. Valerie Gerlach fails to provide a specific and substantial utility for the claimed polypeptides.

#### **IV. Claim Rejections Under 35 U. S. C. § 112, 1<sup>st</sup> Paragraph (Enablement)**

The rejection of claims 1, 4, 29, and 32 under 35 U. S. C. § 112, 1<sup>st</sup> paragraph remains. Newly added claims 49-63 are also rejected under 35 U. S. C. § 112, 1<sup>st</sup>

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paragraph. The basis for this rejection is set forth at pages 2-5 of the previous Office Action (Paper No. 15, November 19, 2002).

Applicants' argument about the patentable utility of the claimed invention has been fully considered but is not deemed to be persuasive for reason set forth above.

The issues related the scope enablement set forth in previous Office action have been resolved in view of Applicants' amendment to the claims.

## **V. Conclusion**

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ruixiang Li  
Examiner  
June 18, 2003

  
**GARY KUNZ**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**